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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,717	10/22/2003	Jonathan S. Stinson	10527-501001	9775

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EXAMINER

MORILLO, JANEL COMBS

ART UNIT	PAPER NUMBER
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1742

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/690,717

Applicant(s)

STINSON, JONATHAN S.

Examiner

Janelle Combs-Morillo

Art Unit

1742

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 22, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 30-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 042604.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention: Pt, Pd, Ir, Rh, Au, Ag, and Pb.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 27-33, 35, and 37-39 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Tu Nguyen on August 10, 2004 a provisional election was made without traverse to prosecute the invention of Pt, claims 1-26, 34, 36, 41-59. Affirmation of this election must be made by applicant in replying to this Office action.

Claim Objections

3. Claims 14-17, 33, 37, and 52-55 are objected to because of the following informalities: it is unclear where the martensitic phase is from- i.e. how can the alloy be $\geq 90\%$ martensitic (cl. 17) and the base is Pt not Fe? Appropriate correction/explanation is required.
4. Claim 20 is objected to because of the following informalities: claim 20 appears to be missing a value of tensile strength- said claim reads: "the alloy has a tensile strength of greater than about an ultimate tensile strength of 140 ksi".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 4-7, 13-23, 37-41, 44-47, 49-54, 56-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Aoyama et al. (US 6,666,930 B2).

Aoyama teaches a Pt-Fe alloy permanent magnet to be used in dental magnetic attachments (column 1 lines 13-14, 59-63), which qualifies as a medical device. Aoyama teaches said Pt alloy magnets exhibit excellent strength, toughness, and corrosion resistance (column 1 lines 61-64). Example 1 of Aoyama is drawn to an alloy with 58at% Fe and 42at% Pt, which converts to 72wt% Pt and 28wt% Fe, which falls within the presently claimed alloying ranges (claims 1, 4-8, 13, 41, 44-47, 51). Said claims also mention various elements not mentioned by the prior art of Aoyama, however the instant claims do not mention a minimum amount of said elements (i.e. "less than about 22 weight percent of chromium", etc.). Because Aoyama teaches an example within the presently claimed alloying ranges, it is held that the Pt-Fe alloy taught by Aoyama anticipates the presently claimed invention.

Concerning claims 18-21, 38-40, and 56-59, which mention properties such as pitting resistance, hardness, TS, and density, the examiner asserts that "products of identical chemical composition can not have mutually exclusive properties." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). A chemical composition and its properties are inseparable where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are inherently present. See MPEP 2112.01.

Concerning claims 14-17, 33, 37, and 52-55, which mention a martensitic structure (cl. 14, 52, fully martensitic; cl. 15, 33, 37, 53, $\geq 50\%$ martensitic; cl. 16, 54 $\geq 70\%$ martensitic; cl. 17, 55 $\geq 90\%$ martensitic) because Aoyama teaches a substantially overlapping alloy

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composition, then substantially the same phase (including fully martensitic, would necessarily include the other ranges of % martensite) is inherently expected to occur.

7. Claims 1, 4-8, 13-23, 37-41, 44-47, 50-54, and 56-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Cook (US 4,929,420).

Cook teaches a Pt alloy to be used in dental prostheses (column 1 lines 47, 53), which qualifies as a medical device. Example 1 of Cook is drawn to an alloy with 80.19%Pt, 14.15% Ir, and 5.66% In. Cook further teaches said alloy contain a small Fe impurity (up to 1.5wt%, column 2 lines 52-55). Therefore, the alloy taught by Cook falls within the presently claimed alloying ranges (claims 1, 4-8, 13, 41, 44-47, 50, 51). Said claims also mention various elements not mentioned by the prior art of Cook, however the instant claims do not mention a minimum amount of said elements (i.e. "less than about 22 weight percent of chromium", etc.). Because Cook teaches an example within the presently claimed alloying ranges, it is held that the Pt alloy taught by Cook anticipates the presently claimed invention.

Concerning claims 18-21, 38-40, and 56-59, which mention properties such as pitting resistance, hardness, TS, and density, as stated above, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are inherently present. See MPEP 2112.01.

Concerning claims 14-17, 37, and 52-55, which mention a martensitic structure, because Cook teaches a substantially overlapping alloy composition, then substantially the same phase is inherently expected to occur.

8. Claims 1, 3, 4-9, 13-21, 37-41, 43-47, 50-59 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 57-043948A (JP'948).

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JP'948 teaches a Pt alloy to be for ornamental products, wherein said alloy comprises (in weight%): 84-96% Pt, 1.5-5% Mo (abstract). Example 1 of JP'948 is drawn to an alloy with 85%Pt, 2.5% Mo, 2.5% Fe, 10% Co, which falls within the presently claimed alloying ranges (instant alloy claims 1, 4-8, 13, 41, 44-47, 50, 51). Example 5 of JP'948 comprises 95% Pt, which meets instant claims 9 and 55. Said alloy claims also mention various elements not mentioned by the prior art of JP'948, however the instant claims do not mention a minimum amount of said elements (i.e. "less than about 22 weight percent of chromium", etc.).

JP'948 does not mention said alloy is used for a medical device (indep. cl. 1, 37). The phrase "medical device", is held to define merely an intended use for the alloy composition (said limitation does not denote a particular specific mechanical configuration). Because the prior art teaches an alloy good workability and mechanical strength (abstract), said alloy appears to be inherently capable of performing said intended use as recited in the preamble, See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997), MPEP 2111.02.

Because JP'948 teaches an example within the presently claimed alloying ranges, it is held that the Pt alloy taught by JP'948 anticipates the presently claimed invention.

Concerning claims 14-17, 33, 37, and 52-55, which mention a martensitic structure, because JP'948 teaches a substantially overlapping alloy composition, then substantially the same phase is inherently expected to occur.

Concerning claims 18-21, 38-40, and 56-59, which mention properties such as pitting resistance, hardness, TS, and density, as stated above, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are inherently present. See MPEP 2112.01.

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9. Claims 1, 2, 4-9, 13-21, 37-42, 44-47, 50-59 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 61-133339A (JP'339).

JP'339 teaches a Pt alloy to be for ornamental products, wherein said alloy comprises (in weight%): 84-96% Pt, 1-10% Cr (abstract). Example 2 of JP'339 is drawn to an alloy with 90%Pt, 7% Cr, which falls within the presently claimed alloying ranges (instant alloy claims 1, 4-9, 13, 41, 44-47, 50-51, 55). Said alloy claims also mention various elements not mentioned by the prior art of JP'339, however the instant claims do not mention a minimum amount of said elements (i.e. "less than about 22 weight percent of chromium", etc.). The instant claims mention Fe must be present, however a minimum range of Fe is not specified. However, Fe is held to be in the alloy taught by JP'339 at least on the order of ppm as an impurity.

JP'339 does not mention said alloy is used for a medical device (indep. cl. 1, 37). The phrase "medical device", is held to define merely an intended use for the alloy composition (said limitation does not denote a particular specific mechanical configuration). Because the prior art teaches an alloy good workability and mechanical strength (abstract), said alloy appears to be inherently capable of performing said intended use as recited in the preamble, See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997), MPEP 2111.02.

Because JP'339 teaches an example within the presently claimed alloying ranges, it is held that the Pt alloy taught by JP'339 anticipates the presently claimed invention.

Concerning claims 14-17, 37, and 52-55, which mention a martensitic structure, because JP'339 teaches a substantially overlapping alloy composition, then substantially the same phase is inherently expected to occur.

Concerning claims 18-21, 38-40, and 56-59, which mention properties such as pitting resistance, hardness, TS, and density, as stated above, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are inherently present. See MPEP 2112.01.

10. Claims 10-12, 48, and 49 are rejected under 35 U.S.C. 102(b) or (e) as anticipated by JP'339, JP'948, Cook, or Aoyama. JP'339, JP'948, Cook, and Aoyama are discussed in the paragraphs above.

The prior art of JP'339, JP'948, Cook, or Aoyama do not mention the presence of Ni (cl. 10, 11, 48, 49) or Cu, Mn, Ni, P, Si, N, S, and C (cl. 12). However, a minimum range of said elements is not specified. A range of said elements, at least on the order of ppm as an impurity, is held to be inherent in the alloy taught by JP'339, JP'948, Cook, or Aoyama.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP'948 or JP'339 or Cook (US 4,929,420) or Aoyama (US 6,666,930) in view of Martyniuk et al (US 5,524,338).

The prior art of JP'948, JP'339, Cook, or Aoyama do not teach a medical device made out of said Pt based alloy, wherein said medical device is a surgical instrument or cutting element of a balloon catheter, substantially as presently claimed.

Concerning claims 22, 24, and 25, Martyniuk teaches that medical needles (#42) or parts of microelectrodes (#74, #70) column 7 lines 6, 22-24) can be made out of corrosion resistant Pt-Ir (column 5 lines 46-47). It would have been obvious to one of ordinary skill in the art to form the high Pt content alloys taught by the prior art of JP'948, JP'339, Cook, or Aoyama into a surgical needle or parts of microelectrodes used as medical devices (as taught by Martyniuk), because of the biocompatibility of Pt alloys taught by Martyniuk.

Additionally, concerning claims 23 and 26, though Martyniuk does not mention forming a prosthesis or cutting element, it would have been obvious to one of ordinary skill in the art to form the high Pt alloys taught by the prior art of JP'948, JP'339, Cook, or Aoyama into a variety of medical instruments or implants, including a prosthesis or cutting element, because of the biocompatibility of Pt alloys taught by Martyniuk.

Allowable Subject Matter

13. Concerning claims 34 and 36 (and as applied to generic claims 27-33, and 35), the prior art does not teach or suggest a medical device comprising an alloy with $\geq 50\text{wt}\%$ Pt and a stainless steel.

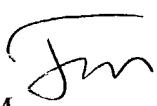
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Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janelle Combs-Morillo whose telephone number is (571) 272-1240. The examiner can normally be reached on 8:30 am- 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JCM
August 23, 2004


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